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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,136	10/12/2000	John F. Engelhardt	875.032US1	7933

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EXAMINER

SULLIVAN, DANIEL M

ART UNIT PAPER NUMBER

1636

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/689,136

Applicant(s)

ENGELHARDT ET AL.

Examiner

Daniel M Sullivan

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 January 2004 and 13 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12,29-84,86 and 87 is/are pending in the application.
- 4a) Of the above claim(s) 37-82 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12,29-36,83,84,86 and 87 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/15/04,4/19/04.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

DETAILED ACTION

This Office Action is a reply to the Papers filed 6 January 2004 and 13 March 2004 in response to the Non-Final Office Action mailed 12 August 2003. Claims 37-82 were withdrawn from consideration and claims 1-12, 29-36 and 83-87 were considered in the 12 August Office Action. Claims 1, 5 and 87 were amended and claim 85 was canceled in the 13 March Paper. Claims 1-12, 29-84, 86 and 87 are pending and claims 37-82 are withdrawn from consideration. Claims 1-12, 29-36 and 83, 84, 86 and 87 are presently under consideration.

Information Disclosure Statement

The Information Disclosure Statements filed 15 January 2004 and 19 April 2004 have been considered. All of the cited references have been reviewed. However, citations of patent applications that are not publicly available and do not name the same inventive entity as the instant application are confidential and cannot be cited on the front page of a published patent. Therefore, applications that are not publicly available and name an inventive entity that is different from the instant inventive entity have been lined through on the considered PTO/SB/08A in order to prevent their publication.

Response to Amendment

Rejection of claim 85 is rendered moot by cancellation of the claim.

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Claim Rejections - 35 USC § 112

Rejection of claims 1-12, 29-36 and 83, 84, 86 and 87 under 35 U.S.C. 112, second paragraph, as being indefinite for reason set forth in the 12 August Office Action is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 102

Claims 1, 4, 5, 10, 12 and 87 stand rejected under 35 U.S.C. 102(b) as being anticipated by Ferrari *et al.* (1996) *J. Virol.* 70:3227-3234 for reasons of record.

In the Remarks filed 6 January 2004, Applicant contends that the claims are free of the art because, “Ferrari *et al.* do not teach identifying an agent that enhances adeno-associated virus transduction after viral binding to the cell membrane and before second strand synthesis, which yields an expressible form of the viral genome” (page 11).

This argument has been fully considered but is not deemed persuasive because, as pointed out in the 6 January Office Action, “Ferrari *et al.* teaches identifying whether the agent alters transduction at the point of uncoating”, which occurs after viral binding to the cell membrane and before second strand synthesis. Although the compound tested in the Ferrari *et al.* publication did not happen to enhance adeno-associated virus transduction at the point of uncoating, identifying a compound having that activity is inherent to the method of Ferrari *et al.* MPEP §2112 states, “[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. §102 and 35 U.S.C. §103...This same rational should also apply to product, apparatus or

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process claims claimed in terms of function, property or characteristic” (emphasis added). The method of Ferrari *et al.* clearly has the function of identifying a compound after viral binding to the cell membrane and before second strand synthesis even if the compound that Ferrari *et al.* happened to test in the method did not have that activity. Therefore, the method of Ferrari *et al.* is the same as the method claimed.

Applicant’s arguments have been fully considered but are not deemed persuasive; therefore, the claims stand rejected under 35 U.S.C. §102(b) as anticipated by Ferrari *et al.*

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12, 29-36 and 83, 84 and 86 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The MPEP states, “[i]f new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. §112, first paragraph-written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981).” (MPEP § 2163.06). The MPEP further states, “[w]hen the issue arises, the fundamental factual inquiry is whether a claim defines an

invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in the application” (*Id.*, § 2163.02). The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of 35 U.S.C. 112, first paragraph. See, e.g., *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996).

In the instant case, claim 1 has been amended such that it reads on any method comprising identifying an agent that enhances adeno-associated virus transduction of a mammalian cell after viral binding to the cell membrane and before second strand synthesis. Thus, the claim now encompasses methods that do not comprise the step of “contacting the mammalian cell with an agent”. There is no support in the originally filed specification and claims for a method that does not comprise the step of contacting a cell with a test agent. Therefore, the scope of amended claim 1, and all claims depending therefrom, is broader than the method as contemplated in the originally filed application.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-12, 29-36 and 83, 84 and 86 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in failing to set forth a terminal process step that clearly relates back to the preamble. The claim does not, in fact, contain a preamble; therefore, it is unclear what process steps, other than the step explicitly set forth in the claim, might be comprised in the method. For example, does the claim encompass a therapeutic method comprising identifying an agent that enhances adeno-associated virus transduction of a mammalian cell and additional treatment steps? Does the claim encompass a method of making a transgenic animal comprising identifying an agent that enhances adeno-associated virus transduction of a mammalian cell and additional steps for producing the transgenic animal? In the absence of a preamble stating the desired outcome of the method and a terminal process step that clearly relates back to the preamble, it is not possible to ascertain what is being claimed.

Claims 2-12, 29-36 and 83-86 are indefinite insofar as they depend from claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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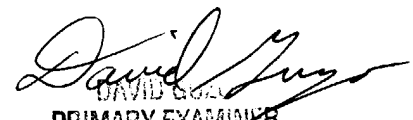
the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS


DAVID M. SULLIVAN
PRIMARY EXAMINER